

**SYSTEM AND METHOD FOR PATIENT MONITORING USING A
5 REFERENCE BASELINE FOR USE IN AUTOMATED PATIENT CARE**

Cross-Reference to Related Applications

This patent application is a continuation of U.S. patent application, Serial
No. 09/686,713, filed October 10, 2000, pending, which is a divisional of U.S.
Patent No. 6,221,011, issued April 24, 2001, the priority filing dates of which are
10 claimed and the disclosures of which are incorporated by reference.

Field of the Invention

The present invention relates in general to automated data collection and
analysis, and, in particular, to a system and method for patient monitoring using a
reference baseline for use in automated patient care.

Background of the Invention

15 Implantable pulse generators (IPGs) are medical devices commonly used
to treat irregular heartbeats, known as arrhythmias. There are three basic types.
Cardiac pacemakers are used to manage bradycardia, an abnormally slow or
irregular heartbeat. Bradycardia can cause symptoms such as fatigue, dizziness,
20 and fainting. Implantable cardioverter defibrillators (ICDs) are used to treat
tachycardia, heart rhythms that are abnormally fast and life threatening.
Tachycardia can result in sudden cardiac death (SCD). Implantable
cardiovascular monitors and therapeutic devices are used to monitor and treat
structural problems of the heart, such as congestive heart failure, as well as
25 rhythm problems.

Pacemakers and ICDs are equipped with an on-board, volatile memory in
which telemetered signals can be stored for later retrieval and analysis. In
addition, a growing class of cardiac medical devices, including implantable heart
failure monitors, implantable event monitors, cardiovascular monitors, and
30 therapy devices, are being used to provide similar stored device information.

These devices are able to store more than thirty minutes of per heartbeat data.

Typically, the telemetered signals can provide patient device information recorded on a per heartbeat, binned average basis, or derived basis from, for example, atrial electrical activity, ventricular electrical activity, minute ventilation, patient activity score, cardiac output score, mixed venous oxygen score, cardiovascular pressure measures, time of day, and any interventions and the relative success of such interventions. Telemetered signals are also stored in a broader class of monitors and therapeutic devices for other areas of medicine, including metabolism, endocrinology, hematology, neurology, muscular disorders, gastroenterology, urology, ophthalmology, otolaryngology, orthopedics, and similar medical subspecialties.

These telemetered signals can be remotely collected and analyzed using an automated patient care system. One such system is described in a related, commonly-owned U.S. Patent application, Serial No. 09/324,894, filed June 3, 1999, pending. The telemetered signals are recorded by an implantable medical device, such as an IPG or monitor, and periodically retrieved using an interrogator, programmer, telemetered signals transceiver, or similar device, for subsequent download. The downloaded telemetered signals are received by a network server on a regular, e.g., daily, basis as sets of collected measures which are stored along with other patient records in a database. The information is analyzed in an automated fashion and feedback, which includes a patient status indicator, is provided to the patient.

While such a system can serve as a valuable tool in automated, remote patient care, the accuracy of the patient care, particularly during the first few weeks of care, and the quality of the feedback provided to the patient would benefit from being normalized to a reference baseline of patient wellness. In particular, a starting point needs to be established for each individual patient for use in any such system in which medical device information, such as telemetered signals from implantable medical devices, is continuously monitored, collected, and analyzed. The starting point could serve as a reference baseline indicating overall patient status and wellness from the outset of remote patient care.

In addition, automated remote patient care poses a further challenge vis-à-vis evaluating quality of life issues. Unlike in a traditional clinical setting, physicians participating in providing remote patient care are not able to interact with their patients in person. Consequently, quality of life measures, such as how the patient subjectively looks and feels, whether the patient has shortness of breath, can work, can sleep, is depressed, is sexually active, can perform activities of daily life, and so on, cannot be implicitly gathered and evaluated.

Reference baseline health assessments are widely used in conventional patient health care monitoring services. Typically, a patient's vital signs, consisting of heart rate, blood pressure, weight, and blood sugar level, are measured both at the outset of care and periodically throughout the period of service. However, these measures are limited in their usefulness and do not provide the scope of detailed medical information made available through implantable medical devices. Moreover, such measures are generally obtained through manual means and do not ordinarily directly tie into quality of life assessments. Further, a significant amount of time generally passes between the collection of sets of these measures.

Thus, there is a need for an approach to determining a meaningful reference baseline of individual patient status for use in a system and method for providing automated, remote patient care through the continuous monitoring and analysis of patient information retrieved from an implantable medical device. Preferably, such an approach would establish the reference baseline through initially received measures or after a reasonable period of observation. The reference baseline could be tied to the completion of a set of prescribed physical stressors. Periodic reassessments should be obtainable as necessary. Moreover, the reference baseline should preferably be capable of correlation to quality of life assessments.

There is a further need for an approach to monitoring patient wellness based on a reference baseline for use in an automated patient care system. Preferably, such an approach would dynamically determine whether the patient is trending into an area of potential medical concern.

There is a further need for an approach to determining a situation in which remote patient care is inappropriate based on a reference baseline of patient wellness. Preferably, such an approach would include a range of acceptance parameters as part of the reference baseline, thereby enabling those potential patients whose reference baseline falls outside those acceptance parameters to be identified.

Summary of the Invention

The present invention provides a system and method for determining a reference baseline for use in an automated collection and analysis patient care system. The present invention further provides a system and method for monitoring a patient status using a reference baseline in an automated collection and analysis patient care system.

An embodiment of the present invention is a system and method for patient monitoring using a reference baseline for use in automated patient care. One or more reference physiological measures relating to individual patient information recorded during an initial observation period are processed into a reference baseline. One or more updated physiological measures recorded subsequent to the initial observation period are periodically received. The updated physiological measures are compared to the reference physiological measures in the reference baseline to generate a patient status indicator identifying any such substantially non-conforming updated physiological measure.

A further embodiment is a system and method for managing a reference baseline of patient information for use in automated patient care. One or more reference physiological measures recorded during an initial observation period are processed. Each reference physiological measure is representative of at least one of measured or derived data. The reference physiological measures are stored into a reference baseline in a patient care record. One or more updated physiological measures recorded subsequent to the initial observation period are periodically received. Each updated physiological measure is representative of at least one of measured or derived data. The updated physiological measures are

stored into individual measures sets in the patient care record. The updated physiological measures in each individual measures set are compared to the reference physiological measures in the reference baseline. Any such updated physiological measure substantially non-conforming to the corresponding
5 reference physiological measure is identified as part of a patient status indicator.

The present invention provides a meaningful, quantitative measure of patient wellness for use as a reference baseline in an automated system and method for continuous, remote patient care. The reference baseline increases the accuracy of remote patient care, particularly during the first few weeks of care, by
10 providing a grounded starting assessment of the patient's health and well-being.

A collateral benefit of the reference baseline is the removal of physician "bias" which can occur when the apparent normal outward appearance of a patient belies an underlying condition that potentially requires medical attention. The reference baseline serves to objectify a patient's self-assessment of wellness.
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The present invention also provides an objective approach to humanizing the raw measures recorded by medical devices, including implantable medical devices. Using known quality of life assessment instruments, a patient can be evaluated and scored for relative quality of life at a given point in time. The reference baseline of the present invention provides a means for correlating the
20 quality of life assessment to machine-recorded measures, thereby assisting a physician in furthering patient care.

Finally, the present invention improves the chronicling of legal responsibility in patient care. A prescribed course of treatment can be traced back to a grounded point in time memorialized by the reference baseline. Thus, a
25 medical audit trail can be generated with a higher degree of accuracy and certainty based on having an established originating point of reference.

Still other embodiments of the present invention will become readily apparent to those skilled in the art from the following detailed description, wherein is described embodiments of the invention by way of illustrating the best
30 mode contemplated for carrying out the invention. As will be realized, the invention is capable of other and different embodiments and its several details are

capable of modifications in various obvious respects, all without departing from the spirit and the scope of the present invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

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Brief Description of the Drawings

FIGURES 1A and 1B are block diagrams showing a system for monitoring a patient status for an individual patient using a reference baseline in an automated collection and analysis patient care system in accordance with the present invention;

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FIGURE 2 is a block diagram showing the hardware components of the server system of the system of FIGURE 1A;

FIGURE 3 is a block diagram showing the software modules of the server system of the system of FIGURE 1A;

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FIGURE 4 is a block diagram showing the processing module of the server system of FIGURE 1A;

FIGURE 5 is a database schema showing, by way of example, the organization of a reference baseline record for cardiac patient care stored as part of a patient care record in the database of the system of FIGURE 1A;

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FIGURE 6 is a database schema showing, by way of example, the organization of a reference baseline quality of life record for cardiac patient care stored as part of a patient care record in the database of the system of FIGURE 1A;

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FIGURE 7 is a database schema showing, by way of example, the organization of a monitoring record for cardiac patient care stored as part of a patient care record in the database of the system of FIGURE 1A;

FIGURES 8A-8C are flow diagrams showing a method for determining a reference baseline for use in monitoring a patient status in an automated collection and analysis patient care system in accordance with the present invention; and

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FIGURE 9 is a flow diagram showing the routine for processing a reference baseline for use in the method of FIGURES 8A-8C;

FIGURE 10 is a flow diagram showing the routine for processing quality of life measures for use in the method of FIGURES 8A-8C; and

FIGURE 11 is a flow diagram showing the routine for reassessing a new reference baseline for use in the method of FIGURES 8A-8C.

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Detailed Description

FIGURE 1A is a block diagram showing a system 10 for determining a reference baseline 5 of patient status for an individual patient 11 for use in an automated collection and analysis patient care system in accordance with the present invention. An automated collection and analysis patient care system suitable for use with the present invention is disclosed in the related, commonly-owned U.S. Patent application, Serial No. 09/324,894, pending, filed June 3, 1999, the disclosure of which is incorporated herein by reference. A patient 11 is a recipient of an implantable medical device 12, such as, by way of example, an IPG or a heart failure or event monitor, with a set of leads extending into his or her heart. Alternatively, subcutaneous monitors or devices inserted into other organs (not shown) without leads could also be used. The implantable medical device 12 includes circuitry for recording into a short-term, volatile memory telemetered signals, which are stored as a set of collected measures for later retrieval.

For an exemplary cardiac implantable medical device, the telemetered signals non-exclusively present patient information recorded on a per heartbeat, binned average or derived basis and relating to: atrial electrical activity, ventricular electrical activity, minute ventilation, patient activity score, cardiac output score, mixed venous oxygenation score, cardiovascular pressure measures, time of day, the number and types of interventions made, and the relative success of any interventions, plus the status of the batteries and programmed settings. Examples of pacemakers suitable for use in the present invention include the Discovery line of pacemakers, manufactured by Guidant Corporation, Indianapolis, IN. Examples of ICDs suitable for use in the present invention include the Gem line of ICDs, manufactured by Medtronic Corporation, Minneapolis, MN.

In the described embodiment, the patient 11 has a cardiac implantable medical device. However, a wide range of related implantable medical devices are used in other areas of medicine and a growing number of these devices are also capable of measuring and recording patient information for later retrieval.

5 These implantable medical devices include monitoring and therapeutic devices for use in metabolism, endocrinology, hematology, neurology, muscular disorders, gastroenterology, urology, ophthalmology, otolaryngology, orthopedics, and similar medical subspecialties. One skilled in the art would readily recognize the applicability of the present invention to these related implantable medical devices.

10 The telemetered signals stored in the implantable medical device 12 are retrieved upon completion of an initial observation period and subsequently retrieved on a continuous, periodic basis. By way of example, a programmer 14 can be used to retrieve the telemetered signals. However, any form of programmer, interrogator, recorder, monitor, or telemetered signals transceiver
15 suitable for communicating with an implantable medical device 12 could be used, as is known in the art. In addition, a personal computer or digital data processor could be interfaced to the implantable medical device 12, either directly or via a telemetered signals transceiver configured to communicate with the implantable medical device 12.

20 Using the programmer 14, a magnetized reed switch (not shown) within the implantable medical device 12 closes in response to the placement of a wand 14 over the location of the implantable medical device 12. The programmer 14 communicates with the implantable medical device 12 via RF signals exchanged through the wand 14. Programming or interrogating instructions are sent to the
25 implantable medical device 12 and the stored telemetered signals are downloaded into the programmer 14. Once downloaded, the telemetered signals are sent via an internetwork 15, such as the Internet, to a server system 16 which periodically receives and stores the telemetered signals in a database 17, as further described below with reference to FIGURE 2.

30 An example of a programmer 14 suitable for use in the present invention is the Model 2901 Programmer Recorder Monitor, manufactured by Guidant

Corporation, Indianapolis, IN, which includes the capability to store retrieved telemetered signals on a proprietary removable floppy diskette. The telemetered signals could later be electronically transferred using a personal computer or similar processing device to the internetwork 15, as is known in the art.

5 Other alternate telemetered signals transfer means could also be employed. For instance, the stored telemetered signals could be retrieved from the implantable medical device 12 and electronically transferred to the internetwork 15 using the combination of a remote external programmer and analyzer and a remote telephonic communicator, such as described in U.S. Patent No. 5,113,869,
10 the disclosure of which is incorporated herein by reference. Similarly, the stored telemetered signals could be retrieved and remotely downloaded to the server system 16 using a world-wide patient location and data telemetry system, such as described in U.S. Patent No. 5,752,976, the disclosure of which is incorporated herein by reference.

15 The initial set of telemetered signals recorded during the initial observation period is processed by the server system 16 into a set of reference measures and stored as a reference baseline 5 in the database 17, as further described below with reference to FIGURE 3. The purpose of the observation period is to establish a reference baseline 5 containing a set of reference measures
20 that can include both measured and derived patient information. The reference baseline 5 can link "hard" machine-recorded data with "soft" patient-provided self-assessment data from which can be generated a wellness status indicator. In addition, the reference baseline 5 can be used to identify patients for whom remote patient care may be inappropriate and for patient wellness comparison and
25 analysis during subsequent, on-going remote patient care. The reference baseline 5 is maintained in the database 17 and can be reassessed as needed or on a periodic basis.

 Subsequent to the initial observation period, the patient is remotely monitored by the server system 16 through the periodic receipt of telemetered
30 signals from the implantable medical device 12 via the internetwork 15. Feedback is then provided back to the patient 11 through a variety of means. By

way of example, the feedback can be sent as an electronic mail message generated automatically by the server system 16 for transmission over the internetwork 15. The electronic mail message is received by personal computer 18 (PC) situated for local access by the patient 11. Alternatively, the feedback can be sent through
5 a telephone interface device 19 as an automated voice mail message to a telephone 21 or as an automated facsimile message to a facsimile machine 22, both also situated for local access by the patient 11. In addition to a personal computer 18, telephone 21, and facsimile machine 22, feedback could be sent to other related devices, including a network computer, wireless computer, personal
10 data assistant, television, or digital data processor.

FIGURE 1B is a block diagram showing a further embodiment of the present invention in which the patient 11 is monitored by the implantable medical device 12 while engaged in performing a prescribed set of timed physical stressors during an initial observation period or during a subsequent observation
15 period if the patient 11 is being reassessed. The stressors are a set of normal, patient activities and cardiovascular and respiratory maneuvers that allow consistent, reproducible physiological functions to be measured by the implantable medical device 12. These maneuvers include activities such as a change in posture, simple physical exercises, breathing state, including holding
20 breath and hyperventilating, and oxygen challenges. By way of example, the stressors include timed physical activities such as running in place 6, recumbency 7, standing 8, sitting motionless 9, and reprogramming at least one of pacing interventions and pacing modes of the implantable medical device 12, as further described below with reference to FIGURE 5.

25 In a still further embodiment of the present invention, at least one of pacing interventions and pacing modes of the implantable medical device 12 is reprogrammed by the programmer 14 during the initial observation period or during a subsequent observation period if the patient 11 is being reassessed. The patient 11 is then monitored by the reprogrammed implantable medical device 12.

30 FIGURE 2 is a block diagram showing the hardware components of the server system 16 of the system 10 of FIGURE 1A. The server system 16 consists

of three individual servers: network server 31, database server 34, and application server 35. These servers are interconnected via an intranetwork 33. In the described embodiment, the functionality of the server system 16 is distributed among these three servers for efficiency and processing speed, although the functionality could also be performed by a single server or cluster of servers. The network server 31 is the primary interface of the server system 16 onto the internetwork 15. The network server 31 periodically receives the collected telemetered signals sent by remote implantable medical devices over the internetwork 15. The network server 31 is interfaced to the internetwork 15 through a router 32. To ensure reliable data exchange, the network server 31 implements a TCP/IP protocol stack, although other forms of network protocol stacks are suitable.

The database server 34 organizes the patient care records in the database 17 and provides storage of and access to information held in those records. A high volume of data in the form of collected device measures sets from individual patients is received. The database server 34 frees the network server 31 from having to categorize and store the individual collected device measures sets in the appropriate patient care record.

The application server 35 operates management applications, assimilates the reference measures into the reference baseline 5 (shown in FIGURE 1A), and performs data analysis of the patient care records, as further described below with reference to FIGURE 3. The application server 35 communicates feedback to the individual patients either through electronic mail sent back over the internetwork 15 via the network server 31 or as automated voice mail or facsimile messages through the telephone interface device 19.

The server system 16 also includes a plurality of individual workstations 36 (WS) interconnected to the intranetwork 33, some of which can include peripheral devices, such as a printer 37. The workstations 36 are for use by the data management and programming staff, nursing staff, office staff, and other consultants and authorized personnel.

The database 17 consists of a high-capacity storage medium configured to store individual patient care records and related health care information.

Preferably, the database 17 is configured as a set of high-speed, high capacity hard drives, such as organized into a Redundant Array of Inexpensive Disks

5 (RAID) volume. However, any form of volatile storage, non-volatile storage, removable storage, fixed storage, random access storage, sequential access storage, permanent storage, erasable storage, and the like would be equally suitable. The organization of the database 17 is further described below with reference to FIGURES 5-7.

10 The individual servers and workstations are general purpose, programmed digital computing devices consisting of a central processing unit (CPU), random access memory (RAM), non-volatile secondary storage, such as a hard drive or CD ROM drive, network interfaces, and peripheral devices, including user
15 interfacing means, such as a keyboard and display. Program code, including software programs, and data are loaded into the RAM for execution and processing by the CPU and results are generated for display, output, transmittal, or storage. In the described embodiment, the individual servers are Intel Pentium-based server systems, such as available from Dell Computers, Austin, Texas, or Compaq Computers, Houston, Texas. Each system is preferably equipped with
20 128MB RAM, 100GB hard drive capacity, data backup facilities, and related hardware for interconnection to the intranetwork 33 and internetwork 15. In addition, the workstations 36 are also Intel Pentium-based personal computer or workstation systems, also available from Dell Computers, Austin, Texas, or Compaq Computers, Houston, Texas. Each workstation is preferably equipped
25 with 64MB RAM, 10GB hard drive capacity, and related hardware for interconnection to the intranetwork 33. Other types of server and workstation systems, including personal computers, minicomputers, mainframe computers, supercomputers, parallel computers, workstations, digital data processors and the like would be equally suitable, as is known in the art.

30 The telemetered signals are communicated over an internetwork 15, such as the Internet. However, any type of electronic communications link could be

used, including an intranetwork link, serial link, data telephone link, satellite link, radio-frequency link, infrared link, fiber optic link, coaxial cable link, television link, and the like, as is known in the art. Also, the network server 31 is interfaced to the internetwork 15 using a T-1 network router 32, such as manufactured by

5 Cisco Systems, Inc., San Jose, California. However, any type of interfacing device suitable for interconnecting a server to a network could be used, including a data modem, cable modem, network interface, serial connection, data port, hub, frame relay, digital PBX, and the like, as is known in the art.

FIGURE 3 is a block diagram showing the software modules of the server

10 system 16 of the system 10 of FIGURE 1A. Each module is a computer program written as source code in a conventional programming language, such as the C or Java programming languages, and is presented for execution by the CPU as object or byte code, as is known in the art. The various implementations of the source code and object and byte codes can be held on a computer-readable storage

15 medium or embodied on a transmission medium in a carrier wave.

There are three basic software modules, which functionally define the primary operations performed by the server system 16: database module 51, analysis module 53, and processing module 56. In the described embodiment, these modules are executed in a distributed computing environment, although a

20 single server or a cluster of servers could also perform the functionality of these modules. The module functions are further described below beginning with reference to FIGURES 8A-8C.

A reference baseline 5 is established at the outset of providing a patient with remote patient care. The server system 16 periodically receives an initially

25 collected device measures set 57. This set represents patient information which was collected from the implantable medical device 12 (shown in FIGURE 1A) during the initial observation period, as further discussed below with reference to FIGURE 5. In addition, the server system 16 can also periodically receive quality of life measures sets 60 recorded by the patient 11, as further described below

30 with reference to FIGURE 6. Both the initially collected device measures set 57 and quality of life measures set 60 are forwarded to the database module 51 for

storage in the patient's patient care record in the database 52. During subsequent, on-going monitoring for remote patient care, the server system 16 periodically receives subsequently collected device measures sets 58, which are also forwarded to the database module 51 for storage.

5 The database module 51 organizes the individual patient care records stored in the database 52 and provides the facilities for efficiently storing and accessing the collected device measures sets 57, 58 and patient data maintained in those records. Exemplary database schemes for use in storing the initially collected device measures set 57, quality of life measures set 60, and subsequently
10 collected device measures sets 58 in a patient care record are described below, by way of example, with reference to FIGURES 5-7. The database server 34 (shown in FIGURE 2) performs the functionality of the database module 51. Any type of database organization could be utilized, including a flat file system, hierarchical database, relational database, or distributed database, such as provided by
15 database vendors, such as Oracle Corporation, Redwood Shores, California.

 The processing module 56 processes the initially collected device measures set 57 and, if available, the quality of life measures set 60, stored in the patient care records in the database 52 into the reference baseline 5. The reference baseline 5 includes a set of reference measures 59 which can be either
20 directly measured or indirectly derived patient information. The reference baseline 5 can be used to identify patients for whom remote patient care might be inappropriate and to monitor patient wellness in a continuous, on-going basis.

 On a periodic basis or as needed, the processing module 56 reassesses the reference baseline 5. Subsequently collected device measures sets 58 are received
25 from the implantable medical device 12 (shown in FIGURE 1A) subsequent to the initial observation period. The processing module 56 reassimilates these additional collected device measures sets into a new reference baseline. The operations performed by the processing module 56 are further described below with reference to FIGURE 4. The application server 35 (shown in FIGURE 2)
30 performs the functionality of the processing module 56.

5 The analysis module 53 analyzes the subsequently collected device
measures sets 58 stored in the patient care records in the database 52. The
analysis module 53 monitors patient wellness and makes an automated
determination in the form of a patient status indicator 54. Subsequently collected
10 device measures sets 58 are periodically received from implantable medical
devices and maintained by the database module 51 in the database 52. Through
the use of this collected information, the analysis module 53 can continuously
follow the medical well being of a patient and can recognize any trends in the
collected information that might warrant medical intervention. The analysis
15 module 53 compares individual measures and derived measures obtained from
both the care records for the individual patient and the care records for a disease
specific group of patients or the patient population in general. The analytic
operations performed by the analysis module 53 are further described below with
reference to FIGURE 4. The application server 35 (shown in FIGURE 2)
20 performs the functionality of the analysis module 53.

The feedback module 55 provides automated feedback to the individual
patient based, in part, on the patient status indicator 54. As described above, the
feedback could be by electronic mail or by automated voice mail or facsimile.
Preferably, the feedback is provided in a tiered manner. In the described
25 embodiment, four levels of automated feedback are provided. At a first level, an
interpretation of the patient status indicator 54 is provided. At a second level, a
notification of potential medical concern based on the patient status indicator 54 is
provided. This feedback level could also be coupled with human contact by
specially trained technicians or medical personnel. At a third level, the
30 notification of potential medical concern is forwarded to medical practitioners
located in the patient's geographic area. Finally, at a fourth level, a set of
reprogramming instructions based on the patient status indicator 54 could be
transmitted directly to the implantable medical device to modify the programming
instructions contained therein. As is customary in the medical arts, the basic
35 tiered feedback scheme would be modified in the event of bona fide medical

emergency. The application server 35 (shown in FIGURE 2) performs the functionality of the feedback module 55.

FIGURE 4 is a block diagram showing the processing module 56 of the server system 16 of FIGURE 1A. The processing module 53 contains two functional submodules: evaluation module 70 and acceptance module 71. The purpose of the evaluation module 70 is to process the initially collected device measures set 57 by determining any derived measures and calculating appropriate statistical values, including means and standard deviations, for the reference measures set 59 in the reference baseline 5. The purpose of the acceptance module 71 is to analyze the reference measures set 59 against the acceptance parameters set 72. A patient care record storing a reference measures set 59 substantially out of conformity with the acceptance parameters set 72 could be indicative of a patient for whom remote patient care is inappropriate. Consequently, the acceptance module 71 identifies each patient care record storing at least one reference measure which is substantially non-conforming to a corresponding parameter in the acceptance parameters set 72.

For instance, an acceptance parameter for heart rate might be specified as a mean heart rate within a range of 40-90 beats per minute (bpm) over a 24-hour period. However, a patient care record storing a reference measure falling either substantially above or below this acceptance parameter, for example, in excess of 90 bpm, would be considered substantially non-conforming. The acceptance parameters set 72 are further described below with reference to FIGURE 5.

The evaluation module 70 also determines new reference baselines 73 when necessary. For instance, the new reference baseline 73 might be reassessed on an annual or quarterly basis, as the needs of the patient 11 dictate. Similarly, the new reference baseline 73 might be reassessed for a patient whose patient care record stores a subsequently collected device measures set 58 substantially out of conformity with the reference measures set 59 in the original reference baseline 5. The new reference baseline 73 would be assessed by the processing module 56 using subsequently collected device measures sets 58 during a subsequent observation period.

FIGURE 5 is a database schema showing, by way of example, the organization of a reference baseline record 75 for cardiac patient care stored as part of a patient care record in the database 17 of the system 10 of FIGURE 1A. The reference baseline record 75 corresponds to the reference baseline 5, although

5 only the information pertaining to the set of reference measures in the reference baseline 5 are shown. Each patient care record would also contain normal identifying and treatment profile information, as well as medical history and other pertinent data (not shown). For instance, during the initial observation period, the patient 11 maintains a diary of activities, including the onset of bedtime and

10 waking time, plus the time and dosing of any medications, including non-prescription drugs. The observation period can be expanded to include additional information about the normal range of patient activities as necessary, including a range of potential anticipated activities as well as expected travel times and periods away from home. In addition, information from any set of medical

15 records could be included in the patient care record. The diary, medication, activity, and medical record information and medical test information (e.g., electrocardiogram, echocardiogram, and/or coronary angiogram) is incorporated into the patient care record and is updated with continuing patient information, such as changes in medication, as is customary in the art.

20 The reference measures set 59 stored in the reference baseline record 75 are processed from the initial collected device measures set 57 (shown in FIGURE 3), as further described below with reference to FIGURE 9. The implantable medical device 12 (shown in FIGURE 1A) records the initial collected device measures set 57 during the initial observation period. For

25 example, for a cardiac patient, the reference baseline record 75 stores the following information as part of the reference measures set 59: patient activity score 76, posture 77 (e.g., from barometric pressure), atrial electrical activity 78 (e.g., atrial rate), ventricular electrical activity 79 (e.g., ventricular rate), cardiovascular pressures 80, cardiac output 81, oxygenation score 82 (e.g., mixed

30 venous oxygenation), pulmonary measures 83 (e.g., transthoracic impedance, measures of lung wetness, and/or minute ventilation), body temperature 84, PR

interval 85 (or AV interval), QRS measures 86 (e.g., width, amplitude, frequency content, and/or morphology), QT interval 87, ST-T wave measures 88 (e.g., T wave alternans or ST segment depression or elevation), potassium [K+] level 89, sodium [Na+] level 90, glucose level 91, blood urea nitrogen and creatinine 92, acidity (pH) level 93, hematocrit 94, hormonal levels 95 (e.g., insulin, epinephrine), cardiac injury chemical tests 96 (e.g., troponin, myocardial band creatinine kinase), myocardial blood flow 97, central nervous system injury chemical tests 98 (e.g., cerebral band creatinine kinase), central nervous system (CNS) blood flow 99, and time of day 100. Other types of reference measures are possible. In addition, a well-documented set of derived measures can be determined based on the reference measures, as is known in the art.

In the described embodiment, the initial and any subsequent observation periods last for about one 7-day period during which time the patient might be asked to perform, if possible, repeated physical stressors representative of both relatively normal activity and/or activities designed to test the response of the body to modest activity and physiologic perturbations for use as the baseline “reference” measures that might be recorded daily for a period of one week prior to initiating fee-for-service monitoring. Reference measures taken and derived from the observation period are recorded, processed, and stored by the system 10. The reference measures include both measured and derived measures, including patient activity score 76, posture 77, atrial electrical activity 78, ventricular electrical activity 79, cardiovascular pressures 80, cardiac output 81, oxygenation score 82, pulmonary measures 83, body temperature 84, PR interval 85 (or AV interval), QRS measures 86, QT interval 87, ST-T wave measures 88, potassium [K+] level 89, sodium [Na+] level 90, glucose level 91, blood urea nitrogen and creatinine 92, acidity (pH) level 93, hematocrit 94, hormonal levels 95, cardiac injury chemical tests 96, myocardial blood flow 97, central nervous system injury chemical tests 98, central nervous system (CNS) blood flow 99, and time of day 100. Other combination and derivative measures can also be determined, as known in the art.

An illustrative prescribed set of timed physical stressors for a non-ambulatory patient 11 is as follows:

- (1) Running in place 6: if possible, the patient 11 must run in place for about five minutes;
- 5 (2) Walking (not shown): if possible, the patient 11 must walk for about six minutes and the total distance walked is measured;
- (3) Ascending stairs (not shown): if possible, the patient 11 must ascend two flights of stairs;
- 10 (4) Recumbency 7: if possible, the patient 11 must recline following about two minutes of motionless immobile upright posture. Upon recumbency, the patient 11 must remain as immobile as possible for about ten minutes;
- 15 (5) Standing 8: if possible, the patient 11 must briskly assume an upright standing posture after the ten-minute recumbency 7 and must remain standing without activity for about five minutes;
- (6) Coughing (not shown): if possible, the patient 11 must cough forcefully about three times when in an upright position to record the cardiovascular pressures 80;
- 20 (7) Hyperventilation (not shown): if possible, the patient 11 must hyperventilate over thirty seconds with full deep and rapid breaths to record ventilatory status;
- (8) Sitting motionless 9: when a physician is complicit, the patient 11 must, if possible, use an approximately 2.0 liter per minute nasal cannula while transmitting data for about twenty minutes while sitting to evaluate cardiopulmonary response;
- 25 (9) Program AAI and VVI temporary pacing interventions for five minutes, at low and high rates, if applicable (e.g., 40 bpm and 120 bpm) to evaluate cardiopulmonary response; and
- 30 (10) Test dual site or biventricular pacing modes, if applicable, for approximately 20 minutes to evaluate cardiopulmonary response.

These physical and pacing stimulus stressors must be annotated with date and time of day 100 and correlated with symptoms and the quality of life measures 110. Heart rate, temperature, and time of day are directly measured while the patient activity score and cardiac output score are derived. These
5 physical stressors are merely illustrative in nature and the set of physical and pacing stimulus stressors actually performed by any given patient would necessarily depend upon their age and physical condition as well as device implanted. Also, during the observation period, the temperature is monitored with QT interval shortening and, if the patient is in atrial fibrillation, the patient
10 must undergo an incremental ventricular pacing protocol to assess his or her response to rate stabilization. Finally, a T-wave alternans measurement (not shown) can be integrated into the reference baseline 5 during rest and sinus rhythm activities.

In a further embodiment of the present invention, the reference measures
15 set 59 in the reference baseline 5 are reassessed on an annual or, if necessary, quarterly, basis. In addition, if the reference measures set 59 was recorded during a period when the patient 11 was unstable or recovering from a recent illness, the reference baseline 5 is reassessed when the patient 11 is again stable, as further described below with reference to FIGURE 11.

As further described below with reference to FIGURE 9, the reference
20 measures are analyzed against the acceptance parameters set 72. The acceptance parameters are those indicator values consistent with the presence of some form of chronic yet stable disease which does not require immediate emergency care. In the described embodiment, the acceptance parameters set 72 for the reference
25 measures 59 in the reference baseline record 75 are, by way of example, as follows: cardiac output 81 falling below 2.5 liters/minute/m²; heart rate below 40 bpm or above 120 bpm; body temperature 84 over 101° F and below 97° F; patient activity 76 score of 1.0 or below; oxygenation score 82 of less than 60% mixed venous saturation at rest; pulmonary artery diastolic pressure greater than
30 20 mm Hg at rest; and minute ventilation less than 10.0 liters/minute at rest.

FIGURE 6 is a database schema showing, by way of example, the organization of a reference baseline quality of life record 110 for cardiac patient care stored as part of a patient care record in the database 17 of the system 10 of FIGURE 1A. A quality of life score is a semi-quantitative self-assessment of an individual patient's physical and emotional well being. Non-commercial, non-proprietary standardized automated quality of life scoring systems are readily available, such as provided by the Duke Activities Status Indicator. These scoring systems can be provided for use by the patient 11 on the personal computer 18 (shown in FIGURE 1A) and the patient 11 can then record his or her quality of life scores for periodic download to the server system 16.

For example, for a cardiac patient, the reference baseline quality of life record 110 stores the following information as part of the reference measures set 59: health wellness 111, shortness of breath 112, energy level 113, exercise tolerance 114, chest discomfort 115, time of day 116, and other quality of life measures as would be known to one skilled in the art. Using the quality of life scores 111-116 in the reference baseline quality of life record 110, the patient 11 can be notified automatically when variable physiological changes matches his or her symptomatology.

A quality of life indicator is a vehicle through which a patient can remotely communicate to the patient care system how he or she is subjectively feeling. When tied to machine-recorded physiological measures, a quality of life indicator can provide valuable additional information to medical practitioners and the automated collection and analysis patient care system 10 not otherwise discernible without having the patient physically present. For instance, a scoring system using a scale of 1.0 to 10.0 could be used with 10.0 indicating normal wellness and 1.0 indicating severe health problems. Upon the completion of the initial observation period, a patient might indicate a health wellness score 111 of 5.0 and a cardiac output score of 5.0. After one month of remote patient care, the patient might then indicate a health wellness score 111 of 4.0 and a cardiac output score of 4.0 and a week later indicate a health wellness score 111 of 3.5 and a cardiac output score of 3.5. Based on a comparison of the health wellness scores

111 and the cardiac output scores, the system 10 would identify a trend indicating the necessity of potential medical intervention while a comparison of the cardiac output scores alone might not lead to the same prognosis.

FIGURE 7 is a database schema showing, by way of example, the organization of a monitoring record 120 for cardiac patient care stored as part of a patient care record in the database 17 of the system 10 of FIGURE 1A. Each patient care record stores a multitude of subsequently collected device measures sets 58 (shown in FIGURE 3) for each individual patient 11. Each set represents a recorded snapshot of telemetered signals data which were recorded, for instance, on a per heartbeat or binned average basis by the implantable medical device 12. For example, for a cardiac patient, the following information would be recorded as a subsequently collected device measures set 58: atrial electrical activity 121, ventricular electrical activity 122, minute ventilation 123, patient activity score 124, cardiac output score 125, mixed venous oxygen score 126, pulmonary artery diastolic pressure measure 127, time of day 128, interventions made by the implantable medical device 129, and the relative success of any interventions made 130. In addition, the implantable medical device 12 would also communicate device specific information, including battery status and program settings 131. Other types of collected or combined measures are possible as previously described. In addition, a well-documented set of derived measures can be determined based on the collected measures, as is known in the art.

FIGURES 8A-8C are flow diagrams showing a method 140 for determining a reference baseline 5 for use in monitoring a patient status in an automated collection and analysis patient care system 10 in accordance with the present invention. The method 140 operates in two phases: collection and processing of an initial reference baseline 5 (blocks 141-149) and monitoring using the reference baseline 5 (blocks 150-158). The method 140 is implemented as a conventional computer program for execution by the server system 16 (shown in FIGURE 1A). As a preparatory step, the patient care records are organized in the database 17 with a unique patient care record assigned to each individual patient (block 141).

The collection and processing of the initial reference baseline 5 begins with the patient 11 being monitored by the implantable medical device 12 (shown in FIGURE 1A). The implantable medical device 12 records the initially collected device measures set 57 during the initial observation period (block 142), as described above with reference to FIGURE 5. Alternatively, the patient 11 could be engaged in performing the prescribed set of timed physical stressors during the initial observation period, as described above with reference to FIGURE 1B. As well, the implantable medical device 12 could be reprogrammed by the programmer 14 during the initial observation period, also as described above with reference to FIGURE 1B. The initially collected device measures set 57 is retrieved from the implantable medical device 12 (block 143) using a programmer, interrogator, telemetered signals transceiver, and the like. The retrieved initially collected device measures sets are sent over the internetwork 15 or similar communications link (block 144) and periodically received by the server system 16 (block 145). The initially collected device measures set 57 is stored into a patient care record in the database 17 for the individual patient 11 (block 146). The initially collected device measures set 57 is processed into the reference baseline 5 (block 147) which stores a reference measures set 59, as further described below with reference to FIGURE 9.

If quality of life measures are included as part of the reference baseline 5 (block 148), the set of quality of life measures are processed (block 149), as further described below with reference to FIGURE 10. Otherwise, the processing of quality of life measures is skipped (block 148).

Monitoring using the reference baseline 5 begins with the retrieval of the subsequently collected device measures sets 58 from the implantable medical device 12 (block 150) using a programmer, interrogator, telemetered signals transceiver, and the like. The subsequently collected device measures sets 58 are sent, on a substantially regular basis, over the internetwork 15 or similar communications link (block 151) and periodically received by the server system 16 (block 152). The subsequently collected device measures sets 58 are stored

into the patient care record in the database 17 for that individual patient (block 153).

The subsequently collected device measures sets 58 are compared to the reference measures in the reference baseline 5 (block 154). If the subsequently collected device measures sets 58 are substantially non-conforming (block 155), the patient care record is identified (block 156). Otherwise, monitoring continues as before.

In the described embodiment, substantial non-conformity refers to a significant departure from a set of parameters defining ranges of relative normal activity and normal exercise responses for that patient. Relative normal activity is defined as follows. Note the “test exercise period” refers to running in place, walking, and ascending stairs physical stressors described above:

- (1) Heart rate stays within a range of 40-90 bpm without upward or downward change in mean heart rate ± 1.0 standard deviation (SD) over a 24 hour period;
- (2) Wake patient activity score during awake hours stays within a range of ± 1.0 SD without change in the mean activity score over a 24 hour period with no score equal to the minimum activity score noted during sleep;
- (3) Sleep period activity score stays within a range of ± 1.0 SD of typical sleep scores for that patient for the six to ten hour period of sleep with no score less than the minimum score observed during normal awake behavior during the initial observation period or during normal sleep;
- (4) Minute ventilation 123 during normal awake hours stays within a range of ± 1.0 SD without change in the mean score over a 24 hour period with no score equal to the minimum or maximum minute ventilation 123 noted during the test exercise period or the minimum or maximum minute ventilation 123 noted during the initial observation period;

- 5 (5) Cardiac output score 125 during normal awake hours stays within a range of ± 1.0 SD without change in the mean cardiac output score over a 24 hour period with no score equal to the minimum cardiac output score noted during the test exercise period or the minimum cardiac output score noted during the initial observation period;
- 10 (6) Mixed venous oxygenation score 126 during normal awake hours stays within a range of ± 1.0 SD without change in the mean mixed venous oxygenation score over a 24 hour period with no score equal to the minimum mixed venous oxygenation score noted during the test exercise period or the minimum mixed venous oxygenation score noted during the initial observation period;
- 15 (7) Pulmonary artery diastolic pressure measure 127 during normal awake hours stays within a range of ± 1.0 SD without change in the mean pulmonary artery diastolic pressure measure 127 over a 24 hour period with no score equal to the minimum or maximum pulmonary artery diastolic pressure measure 127 noted during the test exercise period or during the initial observation period;
- 20 (8) Potassium levels [K+] score during normal awake hours stays within a range of ± 1.0 SD without change in the mean K+ levels over a 24 hour period with no score less than 3.5 meq/liter or greater than 5.0 meq/liter noted during the test exercise period or during the initial observation period;
- 25 (9) Sodium levels [Na+] score during normal awake hours stays within a range of ± 1.0 SD without change in the mean Na+ levels over a 24 hour period with no score less than 135 meq/liter or greater than 145 meq/liter during the test exercise period or during the initial observation period;
- 30 (10) Acidity (pH) score during normal awake hours stays within a range of ± 1.0 SD without change in the mean pH score over a 24 hour period with no score equal to the minimum or maximum pH score

test exercise period or the maximum CNS CK levels scores noted during the initial observation period;

- 5 (16) Barometric pressure during normal awake hours stays within a range of ± 1.0 SD without change in the mean barometric pressure score over a 24 hour period with no score equal to the minimum or maximum barometric pressure noted during the test exercise period or the minimum or maximum barometric pressure noted during the initial observation period;
- 10 (17) PR interval (or intrinsic AV interval) of sinus rhythm during normal awake hours stays within a range of ± 1.0 SD without change in the mean PR interval over a 24 hour period with no score equal to the minimum or maximum PR interval noted during the test exercise period or the minimum or maximum PR interval noted during the initial observation period;
- 15 (18) QT interval during normal awake hours stays within a range of ± 1.0 SD without change in the mean QT interval over a 24 hour period with no score equal to the minimum or maximum QT interval noted during the test exercise period or the minimum or maximum QT interval noted during the initial observation period;
- 20 (19) QRS duration during normal awake hours stays within a range of ± 1.0 SD without change in the mean QRS duration over a 24 hour period with no score equal to the maximum QRS duration noted during the test exercise period or the maximum QRS duration noted during the initial observation period;
- 25 (20) ST segment depression or elevation during normal awake hours stays within a range of ± 1.0 SD without change in the mean ST segment depression or elevation over a 24 hour period with no score equal to the maximum ST segment depression or elevation noted during the test exercise period or the maximum ST segment depression or elevation noted during the initial observation period;
- 30 and

- (21) Temperature during normal awake hours stays within a range of \pm 1.0 SD without change in the mean temperature over a 24 hour period with no score equal to the minimum or maximum temperature score noted during the test exercise period or the minimum or maximum temperature noted during the initial observation period.

For an exemplary, non-ambulatory patient with no major impairments of the major limbs, reference exercise can be defined as follows:

- (1) Heart rate increases by 10 bpm for each one point increase in activity score. Note that to be considered “normal exercise,” heart rate generally should not increase when the activity score does not increase at least 1.0 SD above that noted during the twenty-four hour reference period or greater than that observed during any reference exercise periods. Heart rate should decrease to the baseline value over fifteen minutes once activity stops or returns to the baseline activity level;
- (2) Patient activity score 124 rises at least 1.0 SD over that observed in the mean activity score over a 24 hour period or greater than that observed during any reference exercise periods;
- (3) Cardiac output score 125 rises at least 1.0 SD over that observed in the mean cardiac output score over a 24 hour period or within 0.5 SD of the two minute test exercise period. Cardiac output score should increase 0.5 liters per minute with each 10 bpm increase in heart rate period or greater than that observed during any reference exercise periods;
- (4) In conjunction with an increase in activity score and heart rate, mixed venous oxygenation score 126 falls at least 1.0 SD below observed in the mean oxygenation score over a 24 hour period or be less than any oxygenation score observed during the reference exercise periods. Oxygenation score should decrease 5.0 mm Hg

with each 10 bpm increase in heart rate or 1.0 SD increase in cardiac output score during exercise;

- (5) In conjunction with an increase in activity score and heart rate, pulmonary artery diastolic pressure measure 127 rises at least 1.0 SD over that observed in the mean cardiovascular pressure score over a 24 hour period or is greater than that observed during the reference exercise periods;
- (6) In conjunction with an increase in activity score and heart rate, minute ventilation 123 rises at least 1.0 SD over that observed over a 24 hour reference period or greater than that observed during any reference exercise period. Minute ventilation should rise 1.0 liter per minute with each 10 bpm increase in heart rate; and
- (7) In conjunction with an increase in activity score and heart rate, temperature should rise at least 1.0 SD over that observed in the mean temperature over a 24 hour period or greater than that observed during the reference exercise periods. Temperature should rise 0.1° F with each 10 bpm increase in heart rate.

Finally, if the time for a periodic reassessment has arrived or the subsequently collected device measures sets 58 are substantially non-conforming (block 157), the reference baseline 5 is reassessed (block 158) and a new reference baseline 73 determined, as further described below with reference to FIGURE 11. Otherwise, the routine returns.

In the described embodiment, the reference baseline 5 is preferably reassessed on an annual or, if necessary, quarterly basis. In addition, the reference baseline 5 might be reassessed if physiological findings dictate that new interventions might be indicated or if the patient 11 indicates a change in medications and general health status. Other bases for reassessing the reference baseline 5 are feasible.

FIGURE 9 is a flow diagram showing the routine 147 for processing a reference baseline 5 for use in the method 140 of FIGURES 8A-8C. The purpose of this routine is to analyze the initially collected device measures set 57 and

create a reference baseline 5, if possible. First, the acceptance parameters set 72 (shown in FIGURE 3) is defined (block 160) and the reference measures set 59 in the reference baseline 5, including any quality of life measures, are analyzed against the acceptance parameters set (block 161), as described above with
5 reference to FIGURE 5. If the reference measures in the reference baseline 5 are substantially non-conforming to the acceptance parameters set (block 162), the patient care record is identified (block 164). Otherwise, if conforming (block 162), the baseline reference 72 is stored into the patient care record in the database 17 (block 163). The routine then returns.

10 FIGURE 10 is a flow diagram showing the routine 149 for processing quality of life measures for use in the method 140 of FIGURES 8A-8C. The purpose of this routine is to process and store a collected quality of life measures set 60 into the reference baseline 5. Collected quality of life measures sets 60 are periodically received by the server system 16 over the internetwork 15 or similar
15 communications link (block 170). The quality of life measures were previously recorded by the patient 11 using, for example, the personal computer 18 (shown in FIGURE 1A) and downloaded onto the internetwork 15 or similar communications link. The collected quality of life measures set 60 is stored into a patient care record in the database 17 for the individual patient 11 (block 171).
20 The collected quality of life measures set 60 is then assimilated into the reference baseline 5 (block 172), as further described above with reference to FIGURE 9. The routine then returns.

FIGURE 11 is a flow diagram showing the routine 158 for reassessing a new reference baseline 73 for use in the method 140 of FIGURES 8A-8C. The
25 purpose of this routine is to reassess a new reference baseline 5 periodically or when necessary. Similar to the collection and assimilation of the initial reference baseline 5, the routine begins with the patient 11 being monitored by the implantable medical device 12 (shown in FIGURE 1A). The implantable medical device 12 records subsequently collected device measures sets 58 throughout a
30 subsequent observation period (block 180), as described above with reference to FIGURE 5. Alternatively, the patient 11 could be engaged in performing the

prescribed set of timed physical stressors, as described above with reference to
FIGURE 1B. As well, the implantable medical device 12 could be reprogrammed
by the programmer 14 during the subsequent observation period, also as described
above with reference to FIGURE 1B. The subsequently collected device
5 measures sets 58 are retrieved from the implantable medical device 12 (block
181) using a programmer, interrogator, telemetered signals transceiver, and the
like. The retrieved subsequently collected device measures sets are sent over the
internetwork 15 or similar communications link (block 182) and periodically
received by the server system 16 (block 183). The subsequently collected device
10 measures sets 58 are stored into the patient care record in the database 17 for the
individual patient 11 (block 184). Finally, the subsequently collected device
measures sets 58 are assimilated into the new reference baseline 73 (block 185),
as further described above with reference to FIGURE 9. The routine then returns.

The determination of a reference baseline consisting of reference measures
15 makes possible improved and more accurate treatment methodologies based on an
algorithmic analysis of the subsequently collected data sets. Each successive
introduction of a new collected device measures set into the database server
would help to continually improve the accuracy and effectiveness of the
algorithms used.

20 While the invention has been particularly shown and described as
referenced to the embodiments thereof, those skilled in the art will understand that
the foregoing and other changes in form and detail may be made therein without
departing from the spirit and scope of the invention.